

# MINI-SYMPOSIUM

## The use of drug eluting stents in single and multivessel disease: results from a single centre experience

G W Mikhail, F Airolidi, D Tavano, A Chieffo, R Rogacka, M Carlino, M Montorfano, G Sangiorgi, N Corvaja, I Michev, D Orlic, C Di Mario, A Colombo

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**Objective:** Drug eluting stents have been shown to reduce the rate of in-stent restenosis in cases where single lesions are treated. The performance of these stents, in patients with multivessel disease and complex lesions, however, remains unknown. Our experience with sirolimus eluting stents in such patients is presented.

**Design and patients:** This study includes all consecutive patients treated at San Raffaele Hospital and EMO Centro Cuore Columbus, Milan, Italy treated with sirolimus eluting stents.

**Results:** Between April 2002 and March 2003, 486 patients with 1027 lesions were treated (437 males, 49 females) with a mean (SD) age of 62.2 (10.5) years. Of all patients studied, 19.1% had single vessel disease, 33.8% had two vessel disease, and 47.1% had three vessel disease. Of the whole study group, 20.3% of patients had diabetes mellitus. A mean (SD) of 2.3 (0.4) stents per patient and 1.1 (0.2) stents per lesion were implanted. The baseline mean reference diameter was 2.7 (0.6) mm with a mean minimal luminal diameter of 0.9 (0.5) mm. Post-stenting, the acute gain was 1.8 (0.6) mm. During hospital stay one patient died (0.2%) and 13 (2.7%) patients had in-hospital myocardial infarction (MI). One patient required urgent repeat percutaneous coronary intervention. Six months clinical follow up was performed in all 347 eligible patients. Six months mortality was 2.0% (n = 7) and acute MI occurred in 0.3% (n = 1). Target lesion revascularisation occurred in 9.5% (n = 33) of the patients and target vessel revascularisation (TVR) in 11.5% (n = 40) of the patients. Major adverse cardiac event rate was 13.8% (n = 48). TVR was 4.5% for single vessel disease and 13.2% for multivessel disease. Diabetes mellitus was the only significant predictor for TVR.

**Conclusion:** The use of drug eluting stents in single and multivessel coronary disease produces good short and medium term results with a low rate of revascularisation. Longer term follow-up is required to confirm these observations.

See end of article for authors' affiliations

Correspondence to:  
Dr Antonio Colombo,  
EMO Centro Cuore  
Columbus, 20145 Milano,  
Via M. Buonarroti, 48,  
Italy; info@emocolumbus.it

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Although the use of stents has reduced the rate of in-stent restenosis compared to balloon angioplasty, the rate of in-stent restenosis continues to be between 15-30%. Several recent trials have shown that clinical outcome, in terms of survival and rate of myocardial infarction (MI), following percutaneous coronary intervention (PCI) for multivessel disease is comparable to that following coronary artery bypass graft surgery (CABG).<sup>1-3</sup> However, with PCI there is an increased rate of repeat revascularisation.<sup>1-4</sup> Recent trials have also shown a significant reduction in the rate of in-stent restenosis with drug eluting stents in patients treated with selected lesions in single vessel disease.<sup>5-7</sup> With more extensive use of these stents, the gap between PCI and CABG is likely to narrow. However, there are currently no published trials on the use of such stents in complex lesions and in patients with multivessel disease. The question, therefore, remains as to whether the low rate of revascularisation with drug eluting stents extends to a broader group of patients with multivessel disease.

If drug eluting stents truly hold the answer to in-stent restenosis, then we could be seeing more patients with multivessel disease receiving PCI in preference to CABG. Furthermore, with the continuing pressure of cost effectiveness in healthcare, there is no doubt that PCI leads to cost savings as compared to surgical revascularisation.

Here, we present our experience of the use of drug eluting stents in patients with both single and multivessel coronary disease in an attempt to highlight some of the issues associated with the use of such stents in the treatment of coronary artery disease in an unselected population.

### METHODS

This was a retrospective observational study which included all consecutive patients, treated between April 2002 and March 2003, with sirolimus eluting stents (Cypher, Cordis Johnson & Johnson, Warren, New Jersey, USA). Patients were recruited from San Raffaele Hospital and EMO Centro Cuore Columbus, Milan Italy. Patients with single and multivessel disease underwent PCI according to routine local protocol.

At the start of the procedure, intravenous heparin was administered at a dose of 70 µg/kg to achieve an activated clotting time > 250 s. Glycoprotein IIb/IIIa inhibitors were administered at the discretion of the operator. Antiplatelet treatment with aspirin 100 mg once daily and clopidogrel 75 mg once daily (started three days before the procedure) or ticlopidine 250 mg twice daily were administered. Patients who were not pre-treated with clopidogrel received a loading dose of 300 mg. Aspirin was continued indefinitely and either ticlopidine or clopidogrel were administered for a minimum period of three months. Patients were treated with sirolimus eluting stents (Cypher, Cordis Johnson & Johnson) according to availability and to operator discretion.

Stent implantation was performed with lesion predilatation or with direct stenting according to the evaluation of the

**Abbreviations:** CABG, coronary artery bypass graft surgery; MACE, major adverse cardiac events; MI, myocardial infarction; MLD, minimum luminal diameter; PCI, percutaneous coronary intervention; RD, reference diameter, TLR, target lesion revascularisation; TVR, target vessel revascularisation

operator. Particular care was taken in order to cover the entire lesion with the stent, and to avoid gaps between adjacent stents, as well as trying to avoid traumatising the vessel outside the stented segment.

MI was defined as Q wave if there was a new Q wave of at least 0.04 s in two or more contiguous electrocardiographic leads associated with an increase in creatine kinase concentrations. Non-Q wave was defined as the absence of new Q waves associated with at least a twofold increase in creatinine kinase plus an elevation of MB isoenzymes at least three times above the normal value.

Major adverse cardiac events (MACE) were defined as death, non-Q and Q wave MI or the need for target vessel revascularisation (TVR) (with either PCI or CABG revascularisation).

Coronary angiograms were analysed using a semi-automated edge contour detection computer analysis system (MEDIS QCA CMS, version 4).<sup>8</sup> Reference diameter (RD), minimal luminal diameter (MLD), percentage diameter stenosis, and lesion length were measured before and after stent implantation. Acute gain (mm) was calculated as: MLD post stenting – MLD at baseline. Relative gain (mm) was calculated as MLD post stenting – MLD at baseline/RD.

### Statistical analysis

Descriptive analyses were used. Results are either quoted as percentages or as mean (SD). Multivariate Cox regression analysis was used to assess predictors for TVR.

### RESULTS

Between April 2002 and March 2003, 486 patients were studied (437 males, 49 females) with a mean age of 62.2 (10.5) years. Patient clinical characteristics including risk factors for coronary artery disease are presented in table 1.

A total of 1027 lesions were treated with sirolimus eluting stents; 40.1% of lesions were treated in the left anterior descending coronary artery (table 2). Of the total number of patients treated, 19.1% had single vessel disease and 47.1% had three vessel disease (table 3). Of the whole study group, 20.3% of patients had diabetes mellitus. A mean of 1.1 (0.2) stents per lesion were implanted with a mean of 2.3 (0.4) stents per patient (table 4). Quantitative coronary analysis was carried out on all lesions at baseline and after stenting. All angiographic measurements are listed in table 5.

Glycoprotein IIb/IIIa inhibitors (abciximab or eptifibatide) were used in over half (52.2%) of the patients according to operator discretion. Of the diabetic patients, 43.4% (n = 43) received glycoprotein IIb/IIIa inhibitors. Three patients (0.62%) from the whole study group, in which glycoprotein IIb/IIIa inhibitors were not used, developed intraprocedural stent thrombosis.

During hospital stay one patient died (0.2%) and 13 (2.7%) patients had in-hospital MI. Two of these patients had Q wave MI. One patient required emergency repeat PCI due to a dissection distal to the stent, which was deployed in the left

**Table 1** Patient characteristics

Total number of patients	486
Age (years)	62.2 (10.5) (range 29–89)
Male	89.9%
Unstable angina	46.1%
Previous myocardial infarction	45.9%
Left ventricular ejection fraction	52.5 (9.6)% (range 20–88)
Diabetes	20.3%
Hypercholesterolaemia	66.3%
Smoking	54.7%
Hypertension	58.8%

**Table 2** Location of the lesions treated

Total number of lesions	1027
Lesion location	
LAD	40.1%
LCX	30.6%
RCA	23.3%
LMS	3.1%
IMA	1.0%
SVG	1.9%
Lesion type	
A	2.1%
B1	18.6%
B2	47.1%
C	32.2%
Total occlusions	8.9%
Bifurcations	27.4%
Trifurcations	1.7%

IMA, internal mammary artery; LAD, left anterior descending artery; LCX, left circumflex artery; LMS: left main stem; RCA, right coronary artery, SVG, saphenous vein graft.

**Table 3** Number of vessels treated

Number of vessels	Percentage of patients (n = 486)	Percentage of vessels treated
1	19.1%	50.2%
2	33.8%	37.7%
3	47.1%	12.1%

**Table 4** Procedural characteristics

Total number of lesions	1027
Stent/lesion	1.1 (0.2)
Stent/patient	2.3 (0.4)
Mean stent length (mm)	26.7 (11.6) (range 8–33)
Primary stenting	15.8%
IVUS performed	11.3%
DCA performed	1.0%
Rotablation performed	0.8%
PCI performed previously at the same site	16.1%
TIMI flow post	
0	0%
1	0%
2	0.2%
3	99.8%
Use of glycoprotein IIb/IIIa inhibitors	52.2%
Intra-procedural stent thrombosis	0.6%

DCA, directional coronary atherectomy; IVUS, intravascular ultrasound; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.

**Table 5** Angiographic measurements at baseline and post-stenting

Total number of lesions	1027
Baseline	
Reference diameter (mm)	2.7 (0.6)
MLD (mm)	0.9 (0.5)
Stenosis (%)	67.8 (17.7)
Length (mm)	16.7 (11.3)
Post-stenting	
Reference diameter (mm)	2.9 (0.7)
MLD (mm)	2.7 (0.5)
Acute gain (mm)	1.8 (0.6)
Relative gain (mm)	0.7 (0.2)

MLD, minimum lumen diameter.

**Table 6** MACE at six months including patients with single and multivessel disease

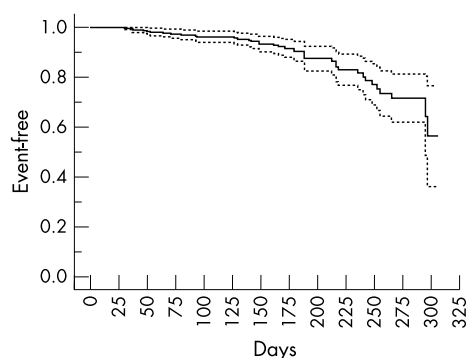
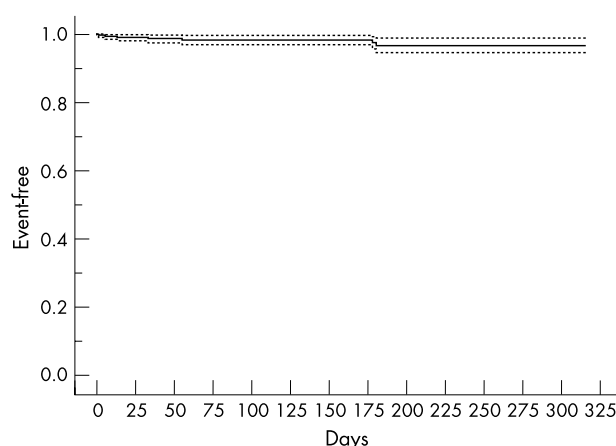
	All patients	Single vessel	Multivessel
Total number of patients	n = 347	66	281
AMI	0.3% (n = 1)	0%	0.4% (n = 1)
Death	2.0% (n = 7)	0%	2.5% (n = 7)
TLR	9.5% (n = 33)	3.0% (n = 2)	11.0% (n = 31)
TVR (by PCI or CABG)	11.5% (n = 40)	4.5% (n = 3)	13.2% (n = 37)

AMI, acute MI; CABG, coronary artery bypass graft surgery; PCI, percutaneous coronary intervention; TLR, target lesion revascularisation; TVR, target vessel revascularisation.

anterior descending artery resulting in acute closure. There were no procedural deaths and emergency CABG was carried out in 0.1% (n = 1) of patients.

Twenty eight patients (5.8%) had unprotected left main stem disease treated with drug eluting stents. Two patients had ostial main stem (7.1%), two had disease in the body of the main stem disease (7.1%), and 24 patients (85.7%) had distal left main disease with bifurcational lesions. Their mean left ventricular ejection fraction was 53 (7)%. In patients with unprotected left main stem, intra-aortic balloon pump was electively used in three (14%) patients and glycoprotein IIb/IIIa inhibitors were used in 15 (54%) patients.

Six months clinical follow up was performed in 347 patients (100% of the eligible patients). Six months mortality was 2.0% (n = 7), acute MI occurred in 0.3% (n = 1) (table 6). Target lesion revascularisation (TLR) was performed in 9.5% (n = 33) of patients and TVR in 11.5% (n = 40) of patients. Thus, total MACE rate was 13.8% (n = 48) (table 6). Of the 347 followed up, 20.0% (n = 68) had diabetes mellitus and of those patients TVR was carried out in 14.7% (n = 10). Kaplan-Meier curves for TVR and death are demonstrated in fig 1 and 2. Diabetes mellitus was the only significant (p < 0.05) predictor for TVR in all patients. At six month follow up, TVR was 4.5% (n = 3) for single vessel disease and 13.2% (n = 37) for multivessel disease. Total MACE for single vessel disease was 4.5% (n = 3) and for multivessel disease was 16.1% (n = 45) (table 6). In those patients who had TVR, restenosis was treated with PCI in all patients (n = 3) with single vessel disease. In patients with multivessel disease, 89.2% (n = 33) underwent revascularisation with PCI and four patients were revascularised with CABG after unsuccessful PCI. Two of the patients who required CABG had diabetes mellitus. In the three patients with single vessel disease, one patient was treated with plain balloon angioplasty, and two patients with additional stenting. In the 33 patients with multivessel disease, two patients had plain balloon angioplasty, one patient had cutting balloon angioplasty, 29 patients had additional stenting, and one patient required atherectomy followed by stenting (table 7).

**Figure 1** Actuarial survival curve for target vessel revascularisation.**Figure 2** Actuarial survival curve for death.

For the unique group of patients with unprotected left main stenting, there were no in-hospital deaths. In-hospital MI (non-Q wave) occurred in two patients (8.3%) of patients. Six month follow up is illustrated in table 8. In these patients TLR was required in 15% and total MACE occurred in 19% (n = 9).

## DISCUSSION

The main findings of this study were: (1) procedural and short term events in an unselected population, with 80.9% prevalence of multivessel disease treated with Cypher stents,

**Table 7** Procedures performed for restenosis

Type of procedure	Single vessel disease (n = 3)	Multivessel disease (n = 37)
POBA	1	2
Cutting balloon	0	1
Stenting with Cypher	1	13
Stenting with Taxus	0	7
Stenting with Cypher + Taxus	0	4
Stenting with bare metal stent	1	5
Atherectomy	0	1
CABG	0	4

CABG, coronary artery bypass graft surgery; POBA, plain balloon angioplasty.

**Table 8** MACE at six months for unprotected left main stem disease

Total number of patients	28
Follow up	6 months
AMI	4% (n = 1)
Death	4% (n = 1)
TLR (by PCI or CABG)	15% (n = 7)

was low, and the short term outcome was comparable to prior reports in less complex and in lower risk patients; (2) the medium term follow up was favourable with an incidence of 2.5% of death and of 0.4% of MI with a low rate of TVR (13.2%); (3) diabetes was the most important predictor of the need for revascularisation.

The main limitation of PCI is restenosis, which is known to be secondary to intimal hyperplasia,<sup>9</sup> and this remains a significant problem which is responsible for the majority of repeat revascularisation procedures. With the introduction of drug eluting stents, the question remains as to whether the reduction in in-stent restenosis seen with such stents, in simple lesions,<sup>5-7</sup> can be extended to their use in multivessel disease.

In our study, 80.9% of patients had multivessel disease and, of those, almost half of the patients (49.8%) received either two vessel (37.7%) or three vessel (12.1%) treatment with drug eluting stents. Patients generally prefer PCI to cardiac surgery. The former is less invasive and is associated with a shorter hospital stay. However, the need for revascularisation is the major drawback. The key question remains as to whether, with the introduction of drug eluting stents and improved interventional techniques, PCI could eventually replace CABG in many patients with multivessel disease.

Various trials have demonstrated that the mortality associated with PCI for patients with multivessel disease is comparable to that of CABG.<sup>1-3</sup> The safety of PCI in such patients is well established and the need for emergency CABG has almost been abolished. In our study, only one patient required emergency CABG. In the ARTS trial (arterial revascularization therapy study),<sup>1</sup> 1205 patients with multivessel disease were randomised to either PCI or CABG. There was no significant difference in mortality between the two groups (2.8% for CABG and 2.5% for PCI,  $p = \text{ns}$ ). Similarly in the ERACI II trial (Argentine randomised study: coronary angioplasty with stenting versus coronary bypass surgery in patients with multiple-vessel disease)<sup>2</sup> which compared PCI and CABG in 450 patients with multivessel disease, freedom from death or myocardial infarction was similar in the two groups. In our study total MACE at six months (acute MI, death, and TVR) occurred in 13.8% of all patients, with death occurring in 2.5% ( $n = 7$ ) of patients with multivessel disease and MI following discharge occurring only in one patient. These rates are lower than those reported in the ARTS trial at one year mainly because of a lower rate of TVR (13.2% at six months  $v$  21%). Data are currently awaited from the ARTS II trial on the use of drug eluting stents in patients with multivessel disease.

In this study we demonstrated that total MACE was 4.5% for single vessel disease and 16.1% for multivessel disease. At six month follow up, TVR for multivessel disease was almost threefold that for single vessel disease (4.5%  $v$  13.2%). This is not an unexpected finding and is in keeping with the results from previous trials as discussed above.

A unique feature of our report is that 38.0% of patients had complex coronary lesions (bifurcation, trifurcation, and chronic total occlusions). In our study, despite the percentage of complex lesions treated, the MACE rate remained low. With the exception of three events of intraprocedural thrombosis, the subsequent incidence of subacute stent thrombosis remained very low with only one event of stent thrombosis associated with unplanned discontinuation of antiplatelet therapy. Glycoprotein IIb/IIIa inhibitors were electively used in over half (52.2%) of the patients. A unique finding was the development of intraprocedural stent thrombosis which occurred in three patients in which glycoprotein IIb/IIIa inhibitors were not used. Our group has previously reported that in our experience, intraprocedural

stent thrombosis has only been seen in drug eluting stents and not in bare metal stents.<sup>10</sup> Furthermore, we have shown that maximum stent length per vessel and the lack of use of glycoprotein IIb/IIIa inhibitors were predictors of intraprocedural stent thrombosis. This unexpected finding has prompted us to increase the use of glycoprotein IIb/IIIa inhibitors when using drug eluting stents. Further follow up, however, will be required in order to assess whether the increase in the use of glycoprotein IIb/IIIa inhibitors can reduce or indeed abolish intraprocedural stent thrombosis.

In the ARTS trial, 21% of patients in the stenting group underwent repeat revascularisation as compared to 3.8% in the CABG group.<sup>1</sup> Similarly in the SOS (stent or surgery) trial, 6% of patients in the CABG group required repeat revascularisation compared to 21% in the PCI group.<sup>4</sup> In our study, 11.5% of all patients underwent TVR. This is a relatively lower rate of restenosis compared to the larger trials. This could be explained by the fact that the total number of patients in our study is significantly lower than that included in the larger trials, and by the fact that the study group included both single and multivessel disease whereas the above mentioned trials were all conducted in multivessel coronary disease. In our study all the patients with single vessel disease underwent TVR with repeat PCI. This was a similar finding in patients with multivessel disease apart from only four patients in this particular group who underwent TVR with CABG after unsuccessful repeat PCI. Of those patients, two were diabetic. This is an encouraging finding as the majority of restenosis seen with sirolimus eluting stents was focal and could easily be treated with repeat PCI.

We have recently reported our findings in patients treated with Cypher stents for single and multivessel disease who required revascularisation.<sup>11</sup> The majority had focal in-stent restenosis while multifocal restenosis was rare, diffuse restenosis absent, and only one of these patients had involvement of the distal edge of the stent.<sup>1</sup> Similar findings were also reported recently in a cohort of 121 patients.<sup>12</sup> This study also observed that in-stent restenosis was mainly associated with such factors as discontinuity in stent coverage, complex lesions, and diabetes. Edge restenosis mainly resulted from local trauma outside the stent.<sup>12</sup>

In our study, diabetes was the only predictor for TVR. Diabetic patients are well known to have an increased rate of restenosis. The substudy from the ARTS trial demonstrated a worse one year outcome in diabetic patients with the lowest event-free survival rate (63.4%) compared with both diabetic patients treated with CABG (84.4%,  $p < 0.001$ ) and non-diabetic patients treated with PCI (76.2%,  $p = 0.04$ ). This was mainly due to the higher incidence of repeat revascularisation in the diabetic patients who were treated with PCI.<sup>13</sup> The reason for the increased rate of restenosis in diabetic patients could be explained by the fact that this group of patients has an increased tendency for neointimal proliferation or vascular thrombosis. This finding is in keeping with the results of our study which showed a worse outcome in diabetic patients despite a high rate of use of glycoprotein IIa/IIIb inhibitors (43.4%) in this group of patients. We showed that 14.7% of diabetic patients underwent TVR (compared to a TVR rate of 11.5% for the whole study group). Furthermore, two of the patients who underwent CABG for restenosis were diabetic. In contrast, subanalysis in the high risk of patients included in the AWESOME trial (angina with extremely serious operative mortality evaluation) showed that diabetic patients ( $> 30\%$ ) with unstable angina had similar survival rates in the CABG and PCI groups.<sup>14</sup> In our study, 20.3% of patients had diabetes and MACE remained low. The fact that diabetes had no impact on mortality or myocardial infarction needs to be confirmed with a longer term follow up. In addition, the number of diabetic patients studied is low and



the benefit of drug eluting stents in this group of patients requires further investigation. The results of the CARDia (coronary artery revascularisation in diabetes) trial, which is currently investigating the use of sirolimus stents in diabetic patients, is eagerly awaited.

Our study did not show that multivessel disease was a predictor for TVR. This was an unexpected finding and could be explained by the fact that the study group at six month follow up is relatively small and that the number of patients with single vessel disease was also small.

The main limitation of the study is the short term follow up period. Longer term follow up in a larger cohort of patients is necessary in order to assess the true rate of restenosis.

## Conclusions

This study has shown that the use of single and multivessel stenting using drug eluting stents is associated with a good clinical outcome with a low rate of in-stent restenosis. If drug eluting stents truly hold the answer to the reduction of in-stent restenosis, PCI could be used in preference to CABG in patients with multivessel disease. Longer term follow up is clearly required.

## Authors' affiliations

G W Mikhail, F Airolidi, D Tavano, A Chieffo, R Rogacka, M Carlino, M Montorfano, G Sangiorgi, N Corvaja, I Michev, D Orlic, A Colombo, San Raffaele Hospital and EMO Centro Cuore Columbus, Milan, Italy  
C Di Mario, The Royal Brompton & Harefield NHS Trust & Imperial College of Science, Technology and Medicine, London, UK

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## ELECTRONIC PAGES

Heart Online case reports: [www.heartjnl.com](http://www.heartjnl.com)

The follow electronic only articles are published in conjunction with this issue of *Heart*.

### Stress, myocardial infarction, and the “tako-tsubo” phenomenon

K A Connelly, A M MacIsaac, V M Jelinek

Emotional distress as a trigger for acute myocardial infarction is beginning to gain credibility as it is recognised that traditional risk factors can account for only half of all myocardial infarctions. Here, three cases of myocardial infarction are presented in the setting of an acute emotional stressor, with coronary angiography showing only minimal coronary artery disease. In all cases striking wall motion abnormalities, mimicking a “tako-tsubo”, were noted with complete resolution within 30 days. This pattern suggests tako-tsubo-like transient left ventricular dysfunction.

(*Heart* 2004;**90**:e52) [www.heartjnl.com/cgi/content/full/90/9/e52](http://www.heartjnl.com/cgi/content/full/90/9/e52)

### Spontaneous coronary artery dissection in the postpartum period: association with antiphospholipid antibody

M Krishnamurthy, R Desai, H Patel

Spontaneous coronary artery dissection (SCAD) is an extremely uncommon cause of myocardial infarction, occurring predominantly in women during or after pregnancy. The exact aetiology is unknown. This report describes a 33 year postpartum woman with diagnosed SCAD who tested positive for anticardiolipin antibody. This is the first case of SCAD in a patient with antiphospholipid antibody. The authors hypothesised that there should be a strong association between them.

(*Heart* 2004;**90**:e53) [www.heartjnl.com/cgi/content/full/90/9/e53](http://www.heartjnl.com/cgi/content/full/90/9/e53)